



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Bernd Riedl et al.

Serial No.: 10/042,226

Group Art Unit: 1614

Filed: January 11, 2002

Examiner: Dwayne C. Jones

For:  $\omega$ -CARBOXYARYL SUBSTITUTED DIPHENYL UREAS AS RAF KINASE INHIBITORS

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98**

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Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

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  - ☒ before the mailing of a first substantive office action (including after filing of an RCE).
- ☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
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- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
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Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
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Cited Materials

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated \_\_\_\_\_.
- ☐ Not required by 37 CFR § 1.98.
- ☒ Copies of the materials listed are attached.

Non-English Language References

☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

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A = document defining the general state of the art

O = non-written disclosure

P = intercalated document

T = document cited to understand the theory or principle underlying the invention

E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date

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[insert necessary translation here]

Other Information

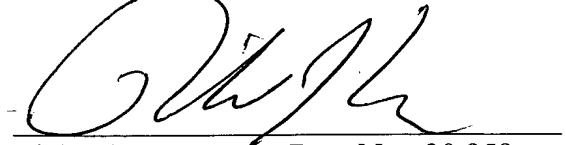
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Respectfully submitted,

A handwritten signature in black ink, appearing to read 'R. Traverso', is written over a horizontal line.

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Attorney Docket No.: BAYER-0024-A

Date: June 14, 2006

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 8

### Complete if Known

Application Number	10/042,226
Filing Date	January 11, 2002
First Named Inventor	Bernd RIEDL et al.
Group Art Unit	1614
Examiner Name	Dwayne C. Jones
Attorney Docket Number	BAYER-0024-A

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		4,546,191				
		5,559,137				
		6,380,218				
		3,284,433				
		5,510,094				
		6,310,068				
		6,525,046				
		6,500,863				

### FOREIGN PATENT DOCUMENTS

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		EP	0690344					
		WO	02/092576					
		WO	02/062763	A2	Bayer Corp.	8-15-2002		
		WO	02/083628	A1	Boehringer Ingelheim Pharmaceuticals Inc.	10-24-2002		
		WO	02/085857	A2	Bayer Corp.	10-31-2002		
		WO	02/085859	A1	Bayer Corp.	10-31-2002		
		WO	97/09973		The Regents Of The University Of California	3-20-1997		
		WO	98/20868					
		WO	98/45268					
		WO	99/28305					
		WO	02/14311					
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		WO	03/099771					
		EP	0709225	B1				

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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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		Blanco, "p38 MAPK signaling cascades: ancient roles and new functions," Bioassays, 22:637-645, 2000	
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		Facts and Comparisons, 1994, 2703-2705	

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		XP-002233466, MEDLINE/NLM, NLM8336809 - [Intra-arterial ACNU, CDDP chemotherapy for brain metastases from lung cancer: comparison of cases with and without intra-arterial mannitol infusion], Iwadata Y et al.	
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Examiner Signature	Date Considered
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		Lowinger, T. B.; Riedl, B.; Dumas, J.; Smith, R. A. "Design and Discovery of Small Molecules Targeting Raf-1 Kinase" Curr. Pharm. Design 2002, 8 (25), 2269.	
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		Siu LL, Awada A, Takimoto CH, Moore MJ, Piccart M, Fiander W, Lathia C, Petrensiuc O: "Phase I study of oral Raf-1 kinase inhibitor BAY 43-9006 in combination with gemcitabine in patients with advanced solid tumors" 39th ASCO meeting, Chicago, IL (2003) Abstract 828.	

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		Richly H, Kupsch P, Passage K, Grugert M, Hilger RA, Kredke S, Voliotis D, Scheulen ME, Seeber S, Strumberg D: "A Phase I clinical and pharmacokinetic study of the Raf kinase inhibitor (RKI) BAY 43-9006 administered in combination with doxorubicin in patients with solid tumors" Int. J. Clin. Pharm. Ther. 2003, 41(12), 620-621.	
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		Wilhelm, S. M.; Carter, C.; Tang, L. Y.; Wilkie, D.; McNabola, A.; Rong, H.; Chen, C.; Zhang, X.; Vincent, P.; McHugh, M.; Cao, Y.; Shujath, J.; Gawlak, S.; Eveleigh, D.; Rowley, B.; Liu, L.; Adnane, L.; Lynch, M.; Auclair, D.; Taylor, I.; Gedrich, R.; Voznesensky, A.; Riedl, B.; Post, L. E.; Bollag, G.; Trail, P. A. "BAY 43-9006 exhibits broad spectrum oral antitumor activity and targets the RAF/MEK/ERK pathway and receptor tyrosine kinases involved in tumor progression and angiogenesis" Cancer Res. 2004, 64(19), 7099-7109.	
		Dumas, J.; Sibley, R.; Riedl, B.; Monahan, M.-K.; Lee, W.; Lowinger, T. B.; Redman, A. M.; Johnson, J. S.; Kingery-Wood, J.; Scott, W. J.; Smith, R. A.; Bobko, M.; Schoenleber, R.; Ranges, G. E.; Housley, T. J.; Bhargava, A.; Wilhelm, S. M.; Shrikhande, A. "Discovery of a New Class of p38 Kinase Inhibitors" Bioorg. Med. Chem. Lett. 2000, 10 (18), 2047.	
		Proceedings of the American Association for Cancer Research - Volume 42 - March 2001 - #4957 A Novel Diphenylurea Raf-1 Kinase Inhibitor (RKI) Blocks the Raf/Mek/Erk Pathway in Tumor Cells. Scott McClelland Wilhelm et al., Bayer Corporation.	

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		Nickel et al., "Carboxylic acid analogues of suramin, potential filaricides," <i>Indian Journal of Chemistry</i> , Vol. 30B, February 1991, p. 182-187	
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		Panka et al., "BAY 43-9006 induces apoptosis in melanoma cell lines," 96th Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA	

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Sheet 7 of 8

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Application Number	10/042,226
Filing Date	January 11, 2002
First Named Inventor	Bernd RIEDL et al.
Group Art Unit	1614
Examiner Name	Dwayne C. Jones
Attorney Docket Number	BAYER-0024-A

### NON PATENT LITERATURE DOCUMENTS

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		Eisen et al., "Phase I trial of BAY 43-9006 (sorafenib) combined with dacarbazine (DTIC) in metastatic melanoma patients," Meeting: 2005 ASCO Annual Meeting, Category: Melanoma, Subcategory: Melanoma, Abstract No. 7508	

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